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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,512	11/16/2001	Oskar Axelsson	NIDN-10389	4557
36335	7590	06/15/2006	EXAMINER	
GE HEALTHCARE, INC. IP DEPARTMENT 101 CARNEGIE CENTER PRINCETON, NJ 08540-6231			JASANI, ASHISH S	
			ART UNIT	PAPER NUMBER
			3737	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/990,512

Applicant(s)

AXELSSON ET AL.

Examiner

Ashish S. Jasani

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35,36,38-60,62,63,65 and 66 is/are rejected.
- 7) ☒ Claim(s) 37,61 and 64 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/16/2001</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged to be correct.

Information Disclosure Statement

1. The information disclosure statement filed 04/11/2003 and 10/20/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.
2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 35, 40-41, 46-47, and 66 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 10-12 of U.S. Patent No. 6311086.

5. Claims 35 and 46-47, and 66 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6278893.

Claim Objections

6. Claim 39 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is evident from claim 35

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that the solution will maintain its polarity. The object of the process is to polarize a solution and image while it is in a hyperpolarized state.

7. Claim 49 objected to because of the following informalities: The parent claim is a method whereas the dependent claim is an apparatus claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 45 and 52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim does not recite a limitation on what compound is used nor does it mention the frequency or wavelength of light.

10. Claim 47 recites the limitation " the paramagnetic species or chromophores" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

12. Claims 35-36, 38-40, and 42-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Dumoulin et al. (USPN 5626137).

With regards to claims 35 and 48, Dumoulin teaches of a nuclear spin polarizing solid dissolved in a physiological saline solution (column 5, line 48), show in Figure 1 as element 159. The solution is then passed to a cryogenic pellet forming means and then the pellets are transferred to the polarizing magnet (column 3, lines 57-63). Figure 1 also shows that the polarized solution is introduced to a subject to be imaged via MRI.

With regards to claims 36 and 46, Dumoulin teaches that the fluid suitable for injection can be a "physiological saline solution" (column 5, line 47).

With regards to claim 38, Dumoulin teaches that "the substance is made to reside in the polarizing magnetic field for a period longer than several times the longitudinal relaxation time, T1, of the substance" (column 2, lines 39-42).

With regards to claim 39, Dumoulin teaches that "once the fluid leaves polarizing magnet 155 it will begin to lose polarization with a time constant equal to its T1. Consequently, it is desirable to deliver the fluid to the patient as quickly as possible.

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This can be done by minimizing the length of catheter 150 and maximizing the flow velocity" (column 5, lines 39-43).

With regards to claim 40, Dumoulin teaches of "a static magnetic field from a main imaging magnet, shown as 125 in FIGS. 1, 3, may be relatively low (such as 0.1 Tesla) to reduce signals from "stationary" tissue and undesired blood pools contributing to the angiographic image" (column 5, lines 53-57).

With regards to claims 42 and 43, Dumoulin teaches of lowering the temperature to 4°K (column 5, line 5).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 41, 44-45, 47, 49-60, 62-63, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumoulin et al. (USPN 5626137) in view of Cates et al (WO 97/37178).

Dumoulin et al. teaches of polarizing a MR imaging agent at low temperatures using a cryogenic chamber at 4°K. Dumoulin also teaches that the agent is mixed with a physiologically safe buffer and then introduced into the patient via a catheter. The

solution is prepared in a 15 T polarizing magnet. Dumoulin does not teach of doping the solid with a paramagnetic species.

Cates et al. teaches of doping either ^{129}Xe or ^3He with Rb or Cs. Cates et al. teaches of mixing means (pages 17-18, lines 18-31 and 6-10 respectively). Cates et al. teaches of a removing the polarizing agent Rb for medical applications (page 27, lines 11-12). Xenon is a water soluble substance.

It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to combine the Dumoulin et al. method of administering a hyperpolarized contrast agent with the Cates et al. method of hyperpolarization method utilizing a paramagnetic polarizing agent. The combination will yield an increase T_1 relaxation time for the imaging agent.

With regards to claim 58 – 60, 62-63, and 65, ^{129}Xe doped with Rb meets the limitations of the aforementioned claims. It is inherent that the solution be sterile and stable at a physiologically temperature for diagnostic value.

With regards to claims 52-55, Cates et al. teaches of optical pumping to polarize the mixture.

Allowable Subject Matter

15. Claims 37, 61, and 64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Driehuys et al. (USPN 6079213)

Montelione et al. (WO 98/57578)

Hoffman et al. (Phys Rev Lett. 1990 Dec 17;65(25):3096-3099.)

Cates et al. (WO 97/37177)

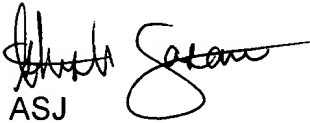
Souza et al. (USPN 5617859)


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ashish S. Jasani whose telephone number is 571-272-8025. The examiner can normally be reached on Mon. - Fri. 9:30 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272 - 4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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